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VIA FEDEX

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket 2004N-0081

Dear Sir or Madam:

I represent Lafarge North America, Inc. ("Lafarge"), which is headquartered in Herndon, Virginia. I am submitting comments on Lafarge's behalf regarding the "Use of Materials Derived from Cattle in Human Food and Cosmetics: Interim Final Rule" published at 69 Fed. Reg. 42256, July 14, 2004.

In short, the Food and Drug Administration (FDA) is seeking comments on an interim final rule to prohibit the use of specified risk material, small intestines from all cattle, material from nonambulatory disabled cattle, material from cattle not inspected, and mechanically separated beef from use in human food, including dietary supplements and cosmetics. The purpose of this rule is to reduce the risk of Bovine Spongiform Encephalopathy (BSE) and variant Creutzfeldt-Jakob (vCJD) disease in the United States. The FDA and other federal agencies have already imposed other new restrictions on the use of certain cattle materials. Each new restriction raises the question of how to dispose of the newly banned material in a safe and efficient manner. Thus far, it does not appear that FDA has given a great deal of attention to this issue, although the IRT Report states that "[e]xclusion and destruction of such a high volume of raw material is a massive burden on all countries currently affected by BSE." 69 Fed. Reg. 42298.

Lafarge has been assisting European countries with the disposal problem, and Lafarge would like to take this opportunity to inform FDA about the beneficial services it may be able to provide with regard to the effective and environmentally safe destruction of ruminant byproducts. We believe, as federal regulatory authorities consider whether additional restrictions should be imposed, they should be aware of the European experience regarding disposal and the opportunities for the same solutions to be employed in the United States.

Lafarge North America is the U.S. and Canada's largest diversified supplier of construction materials such as cement and cement-related products, ready-mixed concrete, gypsum wallboard, aggregates, asphalt and concrete products. The company's materials are used in residential, commercial, institutional and public works construction across the U.S. and Canada. In 2003, net sales exceeded \$3.3 billion.

2004N-0081

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Lafarge North America's majority shareholder is Lafarge (Paris Stock Exchange: LG; NYSE: LR). The Lafarge Group is the world leader in building materials, with 77,000 employees in 75 countries. It holds top-ranking positions in all four of its divisions: Cement, Aggregates and Concrete, Roofing and Gypsum. In 2003, the Lafarge Group recorded sales of more than 13.6 billion euros. Among the most significant of Lafarge Group's business lines is the manufacture of portland cement.

Portland cement is the gray powdery material that forms concrete when mixed with water, sand, and gravel. As such, portland cement is an essential product for the construction of roads, buildings, and other infrastructure elements throughout the world. The term "Portland" cement is not the designation of a brand name. Rather, "Portland" cement is the type of cement that is used to make concrete, as distinguished from other types of cement that may be liquid in form and more closely resemble glue.

Portland cement is manufactured in a process that utilizes a giant furnace known as a cement kiln. For anyone who has not visited a cement manufacturing facility, it is very difficult to convey in words just how massive a kiln can be. For some sense of scale, please refer to the drawing on pages 6-7 of the enclosed brochure, "A New Stone Age: The Making of Portland Cement." (Hereafter referred to as "Exhibit A.")

Cement kilns are typically 300-500 feet long. They are tubular in shape, and the diameter is usually over 20 feet. Kilns consume a tremendous amount of energy to produce the extremely high temperatures necessary for the process to convert raw feed material into "clinker," the precursor to portland cement. (After the nodule-sized "clinker" is produced by the kiln, the clinker is ground with gypsum in a separate process to produce the portland cement product.) The heat and turbulence inside the cement kiln are intense - at some points the temperature reaches 3400° F.

Because cement manufacturing requires so much energy and because traditional energy sources such as fossil fuel are a major production cost, cement manufacturers have long been interested in developing alternative sources of fuel. Throughout Europe and the United States and Canada for a number of years, cement manufacturers have successfully developed programs to utilize industrial wastes, municipal wastes, tires, and other materials as substitutes for fossil fuel. Any of these waste materials that have high "Btu" (British thermal unit) content can serve as fully effective substitutes for fossil fuel in cement kilns.

Cement manufacturers have engaged in such waste-burning practices with full governmental knowledge and approval in both Europe and North America, and such burning is subject to comprehensive air quality regulation and permitting controls. Imposition of such regulations and controls has resulted in a wealth of testing and data on the efficacy and environmental safety of these practices.

Of particular environmental concern is the organic constituents in any waste material that is burned. The extremely high temperature in the cement kiln, coupled with the tremendous turbulence and the long waste residence time in the combustion chamber, allows cement kilns to destroy organic constituents with an efficiency of 99.9999%. See Exhibit A, page 10. (Note: Lafarge has access to a multitude of materials and data showing the testing efficiencies of the cement kiln combustion process, and we did not want to burden FDA at this time with so much material attached to these comments. Lafarge personnel will be happy, upon request and in further conversations with FDA personnel, to supply any such confirmatory data that may be requested.)

Ruminant byproduct material has a high Btu level, which makes it a potentially useful substitute for a portion of fossil fuel being fed to fire cement kilns. Because of BSE concerns in Europe and the UK over the last few years, the use of ruminant byproduct material for animal feed and other commercial uses has, as a precautionary measure, largely been banned since the year 2000. Where have all those millions of tons of materials gone? They have been used as fuel in European cement kilns, and with Lafarge leading the way.

We are submitting for the record a print-out of a PowerPoint presentation entitled "Lafarge's Experience With Meat and Bone Meal." ("Exhibit B.") In this presentation, Lafarge is using the term "Meat and Bone Meal," or "MBM," to generically describe any or all portions of ruminant byproduct material, including but not limited to material often identified as "specified (or specific) risk material" or "SRM."

This burning of MBM in Europe has not only been fully approved by the governments, it was actually initiated at the behest of the French government's Minister of the Environment. See Exhibit B, slide 11. After a series of comprehensive tests on the efficacy and environmental safety of cement kiln burning of MBM sponsored by the French government, there is now full-scale utilization of cement kilns, including Lafarge's, in several European countries. See Exhibit B, slide 15. Lafarge is also now burning MBM in its cement kilns in Japan with the full knowledge and approval of the Japanese authorities. Exhibit B, slide 15.

The slides contained in Exhibit B also show how the management processes employed by Lafarge in Europe and Japan would assure, if similar practices were employed in Canada or the United States, complete protection against worker and/or public exposure to any MBM materials from point of generation, through transportation to the cement kiln, and during storage at the cement kiln before being fed to the kiln for destruction. Exhibit B, slides 14-20.

Just as Lafarge has been doing in Europe, Lafarge's United States cement kilns can play a role in assuring the safe disposition of waste material that has been deemed unsuitable for



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entry into the food chain. We look forward to further discussions with FDA personnel on this important matter. In the meantime, if there are any questions or if you need any further information, please call me at 202-295-4021.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'R. Stoll', written over a horizontal line.

Richard G. Stoll

Exhibits (2)